TAB 2 **Excerpt of Comments from the SDA/CTFA Industry Coalition Regarding the Benefit and Efficacy of Consumer Antiseptic Handwashes (75N-183H; C12, volume 1)**

General Population Products
Antimicrobial Handwash and Antimicrobial Bodywash

It is well-recognized (Larson, 1988; Larson, 1994; Maki, 1978) in hospital settings that antimicrobial cleansing products have a role in infection control. Antimicrobial washes are also used by the general consumer for personal hygiene.

The routine use of personal antimicrobial wash products is beneficial to all. The potential benefits to consumers of antimicrobial washes in addition to cleaning are: (1) to help reduce the incidence of pyogenic infections (Marzulli and Bruch, 1981; Taplin, 1981); (2) to help remove transient organisms which are potentially pathogenic (Noble, 1993); and, (3) to reduce odor-causing bacteria (Marzulli and Bruch, 1981). Washing with antimicrobial washes or with non-medicated washes will remove some bacteria from the skin due to the surfactancy of the base and the mechanical action of the washing procedure. However, antimicrobial washes deposit an active ingredient on the skin that can control the number of organisms that survive and help prevent the colonization of potential pathogens such as *Staphylococcus aureus*, and/or provide increased antimicrobial activity compared to a non-antimicrobial wash product (Marzulli and Bruch, 1981). Washing with non-medicated washes does not provide this reservoir of antimicrobial activity.

Since one out of every three consumer purchases of personal cleansing products is an antimicrobial wash product, it is evident that consumers view antimicrobial washes as an important product class. They view antimicrobial cleansers as good for the entire family, and believe antimicrobial cleansers provide a cleaner feeling and more germ removal than non-medicated products. This high level of acceptance and consumer need is reflected in the marketplace where approximately half (47%) of the households in the United States use antimicrobial wash products. Consumer acceptance is also reinforced by recommendations from physicians. For example, 60% of the pediatricians surveyed have recommend the use of an antimicrobial soap to their patients for a variety of needs. At the 1995 Annual Meeting of the American Academy of Dermatology (AAD), 93.1% of dermatologists surveyed said they recommended antimicrobial soaps. Additionally 82.3% responded that their ability to help manage their patient's medical conditions would be adversely impacted if OTC antimicrobial cleansing products were not available (Dial, 1995a).

Antimicrobial washes are available in many forms (bars, liquids, gels, etc.) and contain a single antimicrobial ingredient. The application of antimicrobial washes is primarily for two different purposes. Products applied to the hands during handwashing reduce organisms on the hands and can reduce the possibility of disease transmission. Antimicrobial bodywashes can play a role in the prevention of pyogenic infections and help control odor-causing bacteria. Whole body use of antimicrobial products can control the number of organisms on the skin and has been demonstrated under laboratory studies to reduce the number of potential pathogens on the skin (Aly and Maibach, 1981). These two purposes call for different modes of action and different spectra of activity. In everyday life consumers encounter situations where they are exposed to a variety of bacteria that have the potential to cause infection. It is well recognized that good personal hygiene can reduce the risk of infection. Antimicrobial washes can play an important role in improving personal hygiene.

The skin is a dynamic environment inhabited by living organisms. It cannot be studied as a whole, but must be subdivided into different micro-habitats. In general the surface can be divided into drier and moister areas depending on the region of the body, the hairy covering, glandular supply, and the type and extent of clothing worn. Additionally, the relative importance of factors that influence the development of skin disease such as etiologic agents, host factors, geo-climatic factors, and occupation are often not apparent, and may be difficult to assess (Jones et al., 1976). For example, different regions of the body vary in their exposure to the air and, therefore, to the evaporative process. Clothing, in general, reduces air movement and maintains a high relative humidity and a constant air temperature immediately adjacent to the skin. In comparison, the hands of most individuals remain uncovered except for short periods of time, show little reaction to changes in body heat, are washed more frequently than any other area of the body, and come in contact with the environment to the greatest degree (Marples, 1965). Therefore, they are the most susceptible to trauma and contamination by pathogenic organisms. All these factors indicate that the hands provide a very special habitat which differs in many ways from the general skin surface. Antimicrobial wash products intended primarily for handwashing must be formulated with this difference in mind, and are discussed below.

Just as the skin can be divided into specific habitats based on many factors, so too should antimicrobial wash products used on the skin be separated according to appropriate usage, efficacy, and attributes.

Efficacy Data

The Agency has requested data to support the efficacy of antimicrobial products for use by consumers and foodhandlers (FDA, 1994). The proprietary nature of this data makes it difficult to prepare a joint submission that would become public record. The industry is in the process of evaluating this highly confidential data with the intent of meeting the December 15, 1995 deadline for submission of data.

Antimicrobial Handwashes

There is consensus in the medical and scientific communities that transfer of transient bacteria via hands is a major factor in the spread of disease (Larson, 1988). Hands can be viewed as unique in three respects. First, hands, more than any other part of the body, are in constant contact with the environment and as such reflect exposure to transient contaminants from many sources. Second, various parts of the hand such as the nail folds and interdigital spaces provide specific microenvironments which can support organisms with varying growth requirements. Third, the flora of the skin of the hands is highly subject to modification because of the exposure to a number of varied household activities.

The importance of the role of handwashing for infection control has been thoroughly reviewed for settings outside the home (Larson, 1988; Bryan et al., 1995). Although there are no definitive studies in the literature within home settings on currently marketed products, there are numerous studies suggesting a role for antimicrobial washes in personal hygiene. Regarding the absence of clearly definitive trials, Larson (Larson and Rotter, 1990) has written, "I'm not convinced that even the definitive study for which we have been lobbying and waiting would, in fact, influence practice. What we know now from natural experiments, epidemiological studies and experimental models is that clean hands are associated with reduced risk of contact-spread infection in a variety of settings...." It can be argued, based on the spread of disease amongst family members, that the added benefit of residual activity and of increased awareness of the need for handwashing reflected in the purchase of antimicrobial consumer products has a role for their use in the home.

Everyone picks up germs from contact with the environment, and antimicrobial soaps help to remove these germs. Broad spectrum activity is preferable because of the wide variety of potential sources of infection. However, immediate kill is not necessarily affected because consumer soaps remove much of the organism load through the surfactancy mechanism but do not provide long-lasting residual activity. In effect, the surfactancy mechanism is broad spectrum and, in conjunction with vigorous washing, is fairly effective (Ayliffe, 1980; Ehrenkranz, 1992). However, consumer handwashing is incomplete, rarely is it as thorough as in the hospital setting, and so a residual action is desirable. Bartzokas et al. (1987) reported that the efficacy of an antimicrobial handwash preparation "was significantly augmented" with repeated handwashing.

The flora on the hands and influencing factors have been studied. The transient bacteria lie free on the skin or are loosely attached with dirt (Rayan and Flourney, 1987). The resident flora is a stable population in both size and composition. Washing readily removes most transients, but the resident flora is removed more slowly. Aly and Maibach

(1988) showed that subjects can have as many as 10^6 colony forming units recoverable from their hands. McGinley et al. (1988) point out that many types of flora are found in the subungual region of the hands and can be detected after handwashing. Peterson (1985) presented data on the normal flora of the hands and the factors that affect the numbers of flora including different household activities like gardening and food preparation. Obviously, the flora that may be present on the hands as transients are greatly influenced by the activity related to a source of contamination and the environmental conditions. For the consumer, these include, among others, food preparation, contact with pets, gardening, and yardwork, contact with other people, daycare, school, work, travel, and recreation. These are examined further below.

Surveys of the bacteria found in the home environment (Scott et al., 1982; Finch et al., 1978; Mendes and Lynch, 1976; Bloomfield, 1978; Roach, 1994) suggested four major sites of household contamination: dry areas (e.g., floors, linens, furniture, clothing), wet areas (e.g., baths, sinks, toilets, drains), food, and people. In many homes, animals (e.g., pets, farm animals) and outside work (gardening, yard work) should be included. Scott et al. (1982) pointed out that although it is accepted that the risk of infection in the general community is lower than that associated with hospitalized patients, increases in the number of outbreaks of household food poisoning cases had been observed. In the survey by Scott et al. (1982), high bacteria counts were found mainly in wet areas associated with sinks, baths, and diaper pails. High bacteria counts also were frequently recovered from washcloths, dishcloths, and cleaning towels. The survey included isolation for *Escherichia coli,* pseudomonads, *S. aureus*, and streptococci. Marples and Towers (1979) further established a model to study how contact transfer of *Staphylococcus* can occur from objects. Borneff et al. (1985) examined households for organisms causing infectious enteritis and found 267 of 4683 samples contained staphylococci. These studies support the need for handwashing and the desirability of antimicrobial soaps.

The shift in recent years from home-based child care to group daycare further extends the household environment because of the likelihood of transmission back to the family and further intrafamilial spread (Goodman et al., 1984; Pickering et al., 1986; Morrow et al., 1991; Chorba et al., 1987; Fornasini et al., 1992). Surveys of the daycare center environment have found contamination of the surfaces, toys, food areas, diaper changing areas, and the hands of children and adults (Ekanem et al., 1983; Van et al., 1991; Osterholm et al., 1992; Holaday et al., 1990; Laborde et al., 1993). With 5.3 to 11 million children in out-of-home daycare in the United States, an important number of families are exposed to conditions where hygiene may be less than satisfactory (Bartlett et al., 1988). Laborde et al. (1993) were able to demonstrate an increased risk of diarrhea associated with fecal contamination levels. They found that toys had the highest coliform bacteria contamination level and that hand contamination strongly affected diarrhea incidence. They state that "hands can be primary vehicles of enteric disease transmission." Dry surfaces, while contaminated, appeared less likely to be significant sources of enteropathogens. Compounding the problem are inadequate personal hygiene practices. One study estimated that staff compliance with handwashing recommendations was only found in 75% of the centers studied (Adiss et al., 1994). The recent work of Laborde et al. (1993) demonstrated a correlation between the contamination level and the increased risk of disease, and reemphasized the obvious need for improved handwashing. Thompson (1994) emphasized the need for frequent handwashing to improve daycare hygiene, " ... studies together emphasize the importance of constant reinforcement of the importance of handwashing, but also the need to train people in how to wash their hands to minimize microbial contamination."

Morrow et al. (1991) and Osterholm et al. (1992) demonstrated the transmission of disease from daycare centers to the home where it is transferred among family members. For example, *Clostridium difficile* is a cause of antibiotic-associated colitis. It has been shown to occur in daycare centers and to be transferred to families. Persons providing at-home care for ill children or the elderly adult have an additional personal hygiene need where antibacterial washes may be useful (Ahmed et al., 1993; Smith, 1984). Using selective media, it was found that contamination with this organism was common in the environment of patients with the disease. It was often found on floors, toilets, bedding, mops, scales, and furniture. The organism was also present less often in areas in which patients known to carry this hardy spore-forming organism had not been present. Air, food, and walls were negative. The organism was isolated from the hands and stools of asymptomatic hospital personnel. It was also found on surfaces in a patient's home. The importance of the various sources of the organism in its spread is not known. It was suggested that enteric isolation precautions, and careful handwashing and cleansing of potentially contaminated surfaces and objects may be worthwhile when cases of antibiotic-associated colitis are identified (Fekety et al., 1981).

Roth and Land (1987) instruct family members to wash hands immediately after touching contaminated objects and surfaces such as soiled laundry to help keep home care from becoming a health hazard to other family members.

Handwashing while at work is most often found with the foodhandling and preparation industry where the consequences of poor personal hygiene can produce outbreaks of disease (Foulke, 1994). Products appropriate for this use have been discussed in a previous section. However, in addition to the obvious exposures inherent in foodhandling and activities like diaper changing in daycare centers, there are a number of other activities encountered at work which lead to exposures to potentially harmful microorganisms. These include handshaking, exposure to ill colleagues in meetings, contact with the public, sharing objects such as public toilets, telephones, exercise equipment and money, as well as other obvious situations such as those encountered by animal handlers or sanitation workers (Noble, 1983). Good personal hygiene is obviously important at work. The Mayo Clinic (1993) points out that it is critical to wash hands after using the bathroom, handling food, handling money, coughing, sneezing, etc. Additionally, Good Manufacturing Practices require handwashing under several circumstances such as before returning to the laboratory or manufacturing floor after using the bathroom.

Bryan et al. (1995) recently updated a previous literature review (Larson, 1988) on the importance of handwashing in reducing the spread of infection. Thirteen non-experimental studies and five experimental studies were identified in the review from settings from the operating room to daycare centers, to an outdoor festival to villages and urban areas of developing countries. These studies and additional work demonstrating the effectiveness of handwashing are summarized below.

Studies in Developing Countries and Non-Institutional Settings

There are several studies from developing countries. These were conducted in an environment conducive to the spread of disease. These data are relevant to conditions found in areas of the United States where hygiene is poor, such as border shanty towns and Indian reservations (Mintz et al., 1995). They are also relevant to other situations, such as daycare (Pickering et al., 1986) and outdoor music festivals (Lee et al., 1991).

Neonatal tetanus remains one of the major causes of death in developing countries. Results of a study on risk factors of neonatal tetanus in Senegal by Leroy and Garenne (1991) suggest that teaching mothers and birth attendants simple hygienic principles and basic techniques may have a significant impact on neonatal tetanus mortality. The skill and behavior of the birth attendant and mother were highly significant risk factors and were associated with high odds ratio and included whether the hands of the person cutting the umbilical cord were washed with soap. Similarly, a study in rural Bangladesh (Hlady et al., 1992) found a significantly lower risk of neonatal tetanus when the person cutting the umbilical cord had washed their hands.

Diarrhea is a major cause of illness globally. Clemens and Stanton (1987) showed in an urban Bangladesh study that significantly more diarrhea occurred in children whose mothers did not wash their hands before food preparation. In a randomized trial in urban Bangladesh to study the effects of an educational intervention program on hygiene and diarrhea rates, Stanton and Clemens (1987) reported that the incidence of diarrhea in the intervention group was 26% lower than in the control group. After intervention, 49% of the test families versus 33% of the control families washed their hands before food preparation. This improvement in personal hygiene was related to the improvement in diarrhea incidence.

Kaltenhalter et al. (1991) conducted a study in Zimbabwe that demonstrated that washing with soap is more effective in reducing fecal bacteria contamination of hands than not using soap. Their data also suggest that an antimicrobial soap would be beneficial beyond plain soap by providing residual activity versus organisms which are found on hands after washing, especially in hot humid conditions.

Kahn (1982) concluded that handwashing had a positive effect on interrupting shigellosis transmission even in unsanitary environments in rural Bangladesh.

Wilson and Chandler (1993) determined from their education program which encouraged handwashing with soap among fifty-seven mothers in Indonesia, that two years after the intervention (1) 79% of mothers were still using hand soap, despite the fact that they now had to buy it themselves, and (2) the community seemed to be benefiting from a sustained reduction in diarrhea episodes due to improved hygiene practices.

In a study conducted in Indonesia (Wilson et al., 1991), children experienced an 89% reduction in diarrhea episodes versus the control period, when their mothers were given soap for handwashing and an explanation of the fecal-oral route of diarrhea transmission.

Verweij et al. (1991) suggest that improving water supply alone did not correlate with an improvement in infectious disease, but the prevelance of infectious skin disease was negatively correlated with the frequency of washing. It was concluded that personal hygiene appears to play an essential role in keeping the prevalence of infectious disease low.

As pointed out by Bryan et al. (1995) inadequate sanitation and poor hygiene are conditions that are not limited to developing countries. In the outbreak described by Lee et al. (1991) an estimated 3,175 women attending a 5-day outdoor music festival contracted shigella gastroenteritis. Limited access to soap and running water by the more than 2,000 volunteer food preparers was suggested as a contributing factor.

Institutions and Schools

Black et al. (1981) first demonstrated the effectiveness of handwashing to prevent diarrhea in daycare centers. Following the initiation of a handwashing program in several daycare centers, the incidence of diarrhea among children in the study was significantly and consistently lower (approximately half) than the incidence in the two control centers over the 35-week study period.

Bartlett et al. (1988) studied diarrheal illness among day care children. Ten randomly selected intervention centers received staff training in procedures to reduce diarrhea transmission and follow up surveillance. Eleven other centers were also followed. The twenty-one centers had higher rates of diarrheal disease than children in home care, but significantly lower rates than centers not in the surveillance. In addition, they suggest that further attention must be directed to effective promotion of hygienic practices among daycare center workers without external monitoring. Finally, an additional study was recommended to identify specific practices, other than handwashing, that could reduce the introduction and transmission of infectious agents in child care groups.

It is recognized that it is often difficult to attribute independent specific effectiveness to an intervention and control program because they are inherently multifaceted. For example Butz et al. (1990) evaluated the effectiveness of an intervention program in daycare homes that included handwashing education, the use of vinyl gloves, disposable diaper changing pads, and an alcohol based hand rinse. Symptoms of enteric illness were lower in the intervention homes, but it was not possible to separate out the effects of each component of the intervention.

Nokes (1983), in an article on nosocomial infections and handwashing, indicates the most effective method of decreasing the spread of infection is effective handwashing.

Nahata (1985), in reviewing disease transmission in daycare centers, wrote, "it has been clearly shown that handwashing can prevent diarrhea and respiratory disease."

Harris et al. (1985), in their study of person to person transmission in an outbreak of enteroinvasive *Escherichia coli* at a school for mentally retarded adults and children in Missouri, stated that control measures to interrupt the transmission of *E. coli* included separation of symptomatic or culture positive students from those who were emphasizing handwashing and were healthy.

Peters and Flick-Filles (1991) reported that use of a hand disinfectant by new mothers helped to significantly reduce the incidence of puerperal mastitis from 2.9% in the control group to 0.65% in the intervention group.

Wilson (1970) showed significant reductions of skin flora with a TCC soap. "In an 18 month ward trial the transmission of staphylococci was significantly reduced by the TCC soap."

Lilly et al. (1979) suggest that repeated washing can result in an equilibrium level of flora where the reduction in density of accessible bacteria is balanced by their replacement by bacteria from the deeper layers of skin. This is important in that Selwyn and Ellis (1972) argue the "care for minimal disinfection" citing the need to maintain resident skin organisms as barriers to infection.

In addition to experimental and field trials, a number of controlled studies have been used to demonstrate antimicrobial effectiveness (Cade, 1951; Finkey et al., 1984; Leyden et al., 1979; Leyden et al., 1981; Price, 1938; Williamson and Kligman, 1965; Yackovich and Heinze, 1985; Yackovich et al., 1986; Yackovich et al., 1989).

The above discussion has clearly pointed out that improved hygiene can help prevent skin infections and interrupt the transmission of infectious disease as transferred by the hands. Therefore, the regular use of an antimicrobial soap for personal cleansing has a recognized role in the prevention of disease. Handwashing is repeatedly cited as the most important infection control measure. It is no less important in the home than in these village and institutional studies cited above.

It can be demonstrated that antimicrobial washes reduce the numbers of organisms on the skin to a greater extent than non-medicated wash. In addition, model systems (Aly, 1994; Scala et al., 1994) have demonstrated the control of potentially pathogenic organisms on the skin. For handwashing to be effective it is important that any product also be acceptable for regular and frequent use by consumers. "As the value of frequent handwashing is well established, the choice of soap brand should be made with a view to encouraging frequent handwashing, while maintaining healthy skin" (Reis-Levy et al., 1984). Antimicrobial ingredients, deposited on the skin, can also be of benefit when washing is perfunctory or inadequate, leaving behind organisms that can cause infection or be transferred to other skin sites. Appropriate degerming for consumers also does not present the risk of removing resident flora to the point of creating a flora shift. Aly and Maibach (1976) showed that prolonged use of antimicrobial soap on skin did not lead to overgrowth of undesirable flora.

Methods

Based on an understanding of the risks involved, the organisms of greatest significance, the population affected, and the products and frequency of use in this category, it is recommended that the following testing procedures and efficacy guidelines be used for antimicrobial handwashes. Both *in vitro* and *in vivo* methods are proposed (Table V).

In vitro testing to establish the spectrum of action of the active ingredient includes Gram positive and Gram negative organisms representative of flora that may be found on the hand as well as one yeast (Table V). The MIC Test (Appendix I) is proposed for testing of active ingredients and finished products only. The test serves to delineate the spectrum of activity of an ingredient or formula, and can be useful for determining active ingredient formulation levels, and active ingredient/vehicle interactions. MIC testing of active ingredients is performed on the organisms listed in Table A. For ingredients to be used in handwash products it is not expected, nor required, that they demonstrate activity against all listed organisms. The MIC testing of handwash products is done against those organisms which are most significant to this category as shown in Table V. Time-Kill tests (Appendix II) are performed by testing the product against the significant organisms

References

The following pages list the references cited in this submission. The references are submitted following this listing.

Addis, D. G., J. J. Sacks, M. Kresnow, J. O'Neil, and G. W. Ryan. 1994. The compliance of licensed US child care centers with National Health and Safety Standards. *Am. J. Public Heath* 84(7): 1161-1163.

Ahmed, N. I., S. Abbas, and E. Shaaban. 1993. Family care of elderly problems. *J. Egypt Public Health Service* 68: 161-177.

Aly, R. 1994. Antimicrobial Soaps: What They Offer. (Manuscript in Preparation).

Aly, R. and H. I. Maibach. 1976. Effect of antimicrobial soap containing chlorhexidine on the microbial flora of skin. *App. Environ. Microbiol.* 31(6): 931-935.

Aly, R. and H. I. Maibach. 1979. Comparative Study on the Antimicrobial Effect of 0.5% Chlorhexidine Gluconate and 70% Isopropyl Alcohol on the Normal Flora of Hands. *App. Environ. Microbiol.* 37: 610-613.

Aly, R. and H. I. Maibach. 1981. *In vivo* methods for testing topical antimicrobial agents. *J. Soc. Cosmet. Chem.* 32: 317 - 323.

Aly R. and H. I. Maibach. 1983. Comparative Evaluation of Chlorhexidine Gluconate (Hibiclens) and Povidone-Iodine (E-Z Scrub) Sponge/Brushes for Presurgical Hand Scrubbing. *Current Therapeutic Research* 34(4): 740 - 745.

Aly, R. and H. I. Maibach. 1987. Skin Infections - Fungal and Bacterial. *Diseases, Diagnoses, Therapy* Hoechst Roussel Pharmaceuticals, Somerville, New Jersey.

Aly, R. and H. I. Maibach. 1988. Comparative antimicrobial efficacy of a 2 minute surgical scrub with chlorhexidine gluconate, povidone iodine, and chloroxylenol sponge-brushes. *Am. J. Infect. Control* 16(4): 173-177.

Association of Official Analytical Chemists. Chlorine (Available) in Disinfectants. 1995. In AOAC Official Methods of Analysis of the Association of Official Analytical Chemists. 16 Edition. Washington, D. C. p. 8.

Association of Operating Room Nurses (AORN). 1990. Recommended practices: surgical hand scrubs. *AORN J.* 52: 830-6.

Association of Operating Room Nurses (AORN). 1993. 1993 Standards & Recommended Practices. AORN, Inc. Denver, CO. pp. 129-133.

ASTM E-1589-94. 1994. Standard Test Method for Evaluation of First Aid Antiseptic Drug Products. *Annual Book of ASTM Standards* 11.04. pp. 1490-1492.

Ayliffe, G. A. J. 1980. The effect of antimicrobial agents on the flora of skin. *J. Hosp. Infect.* 1: 111-124.

Ayliffe, G. A. 1984. Surgical Scrub and Skin Disinfection. *Infect Control* 5: 23 - 27.

Ayliffe, G. A., J. R. Babb, K. Bridges, H. A. Lilly, E. J. Lowbury, J. Varney, and M. D. Wilkins. 1975. Comparison of Two Methods for Assessing the Removal of Total Organisms and Pathogens from the Skin. *J. Hyg. (Camb.)* 75: 259 - 274.

Ayliffe, G. A., J. R. Babb, J. G. Davies, S. W. Newsom, C. Rowland, J. H. Platt, and B. Mason. 1990. Hygienic hand disinfection tests in three laboratories. *J. Hosp Infect.* 16: 141-149.

Ayliffe, G. A., J. R. Babb, and A. H. Quaraishi. 1978. A test for 'hygienic' hand disinfection. *J. Clin. Pathol.* 31: 923-928.

Babb, J. R., J. G. Davies, and G. A. Ayliffe. 1991. A Test Procedure for Evaluating Surgical Hand Disinfection. *J. Hosp. Infect.* 18: 41 - 49.

Baquero, F., C. Patron, R. Canton, and M. Martinez Ferrer. 1991. Laboratory and *in vitro* testing of skin antiseptics: A prediction for in-vivo activity? *J. Hosp. Infect.* 18 (suppl. B): 5-11.

Bartlett, A. V., B. A. Jarvis, V. K. Ross, T. M. Katz, M. A. Dalia, S. I. Englender, and L. J. Anderson. 1988. Diarrheal illness among infants and toddlers in day care centers: effects of active surveillance and staff training without subsequent monitoring. *Am. J. Epidemiol.* 127(4): 808-17.

Bartzokas, C. A., J. E. Corkill, and T. Makin. 1987. Evaluation of the Skin Disinfecting activity and cumulative effect of chlorhexidine and Triclosan handwash preparations on hands artificially contaminated with Serratia marcescens. *Infect. Control* 8(4): 163-167.

Bauer, T. M., E. Ofner, H. M. Just, H. Just, and F. D. Daschner. 1990. An epidemiological study assessing the relative importance of airborne and direct contact transmission of microorganisms in a medical intensive care unit. *J. Hosp. Infect.* 15: 301-309.

Bean, N. H., P. M. Griffin, J. S. Goulding, and C. B. Ivey. 1990. Foodborne Disease Outbreaks, 5-year Summary 1983-1987. *J. Food Protection* 53: 711-728.

Beauregard, S. and G. A. Gilchrest. 1987. A Survey of Skin Problems and Skin Care Regimens in the Elderly. *Arch. Dermatol.* 12: 1638-43.

Ben-Amitai, D. and S. Ashkenazi. 1993. Common bacterial skin infections in childhood. *Pediatric Annals* 22: 225 - 227; 231-233.

Bendig, J. W. 1990. Surgical Hand Disinfection: Comparison of 4% Chlorhexidine Detergent Solution and 2% Triclosan Detergent Solution. *J. Hosp. Infect.* 15: 143 - 148.

Bennett, J. V. and S. D. Holmberg. 1987. In Amler, R. W. and H. B. Dull (Eds.) Closing the Gap: The Burden of Unnecessary Illness. Oxford University Press, New York. pp. 102-114.

Black, R. E., A. C. Dykes, and K. E. Andersen. 1981. Handwashing to Prevent Diarrhea in Day Care Centers. *Am. J. Epidemiol.* 113: 445-451.

Bloomfield, S. F. 1978. A review: The use of disinfectants in the home. *J. Appl. Bacteriol.* 45: 1-38.

Borneff, J., J. R. Wittig, M. Borneff, and G. Hartmetz. 1985. Untersuchungen uber das vorkommen von Enteritis - Erreggen in Haushalt--eine Pilotstudie. *Zbl. Bakteriol. Microbiol. Hyg. I. Abt.* 180(2-3): 319-334.

Boyce, J. M., G. Potter-Bynoe, S. M. Opal, L. Dziobek, and A. A. Medeiros. 1991. A Common Source Outbreak of Staphylococcus epidermidis Infections among Patients Undergoing Cardiac Surgery. *J. Infectious Disease* 161: 493-499.

Bruch, M. 1981. Newer germicides: What they offer. In Maibach, H. I.(Ed.) Skin Microbiology: Relevance in Clinical Infection. Springer-Verlag, New York. pp. 103-112.

Bruch, M. K. 1991. Methods of testing antiseptics; Antimicrobials used topically in humans and procedures for hand scrubs. In Block, S. S. (Ed.) Disinfection, Sterilization, and Preservation, Fourth Edition, Lea & Febiger, Philadelphia. pp. 1028-1046.

Bryan, F. L. 1988. Risks of Practices, Procedures and Processes that Lead to Outbreaks of Foodborne Diseases. *J. Food Protection* 51(8): 663-673.

Bryan, F. L. and M. P. Doyle. 1995. Health Risks and Consequences of Salmonella and Campylobacter jejuni in Raw Poultry. *J. Food Protection* 58: 326-344.

Bryan, J., J. Cohran, and E. Larson. 1995. Handwashing: A Ritual Revisited. In Rutala, W. A. (Ed.) Chemical Germicides in Healthcare International Symposium, 1994. Assoc. For Professionals in Infection Control and Epidemiology. Wash., D. C., Polyscience Publishers, Morin Heights, PQ, Canada. pp. 163-178.

Butz, A. M., E. Larson, P. Fosarelli and R. Yolken. 1990. Occurrence of infectious symptoms in children in day care homes. *Am. J Infect. Control* 6: 347-353.

Cade, A. R. 1951. A method for testing degerming efficacy of hexachlorophene soaps. *J. Soc. Cosmet. Chem.* 2: 281-290.

Centers For Disease Control (CDC). 1986. Nosocomial Infection Surveillance, 1984. MMWR CDC Surveill. Summ. 35(no. 1ss): 17ss. **(Reference not available. Will be provided at a later date.)**

Chorba, T. L., R. A. Meriwether, B. R. Jenkins, R. A. Gunn, and J. N. MacCormack. 1987. Control of a non-foodborne outbreak of Salmonellosis: day care isolation. *Am. J. Public Health* 77(8): 979-981.

Clemens, J. D. and B. F. Stanton. 1987. An educational intervention for altering water-sanitation behaviors to reduce childhood diarrhea in urban Bangledesh I. Application of the case control method for development of an intervention. *Am. J. Epidemiol.* 125: 284-91.

Code of Federal Regulations. 1994. Volume 21, Part 178.1010.

Custer, M. D. and V. A. Allen. 1978. The Case for Simplified Wound Infection Control: A Community Hospital Experience. *Virginia Medical* 105: 431 - 434.

deWit, J. C., G. Broekhuizen, and E. H. Kampelmacher. 1979. Cross-contamination during the preparation of frozen chickens in the kitchen. *J. Hyg. (Camb.)* 83: 27-32.

Dial Corporation. 1995a. Survey of Dermatologists.

Dial Corporation. 1995b Consumer Survey Communique.

Dillon, H. C. 1968. Impetigo Contagiosa: Suppurative and non-suppurative complications. I. Clinical, bacteriologic and epidemiologic characteristics of impetigo. *Amer. J. Diseases Children* 115: 530-541.

Doughty, D., J. Jaramillo, and E. Spengler. 1990. Methods for Assessing the Mildness of Facial Cleansing Products. Preprints of the 16th IFSCC Congress, New York City, NY, October 8-11, 1990, 468-477.

Duncan, W. C., G. Dodge, and, J. M. Knox. 1969. Prevention of Superficial Pyogenic Skin Infections. *Arch. Dermatol.* 99: 465-468.

Ehrenkranz, N. J. 1992. Bland soap handwash or hand antisepsis? The pressing need for clarity. *Infect. Control Hosp. Epidemiol.* 13: 299-301.

Ehrenkranz, N. J. and B. C. Alfonso. 1992. Failure of Bland Handwash to Prevent Hand Transfer of Patient Bacteria to Urethral Catheters. *Infect. Control Hosp. Epidemiol.* 12: 654-662.

Ehrenkranz, N. J. and S. J. Pfaff. 1991. Mediastinitis Complicating Cardiac Operations: Evidence of Postoperative Causation. *Reviews of Infectious Diseases* 13: 803-814.

Eigen, E., A. Legenyei, and S. Weiss. 1975. An *in vivo* Method for the Detection of Residual Antimicrobial Activity on Human Skin. *J. Soc. Cosmet. Chem.* 26: 411-425.

Eitzen, H. E., M. A. Ritter, M. L. French, and T. J. Gioe. 1979. A Microbiological In-Use Comparison of Surgical Hand-washing Agents. *The Journal of Bone and Joint Surgery* 61-A: 403-406.

Ekanem, E., H. L. Dupont, L. K. Pickering, B. J. Selwyn, and C. M. Hawkins. 1983. Transmission dynamics of enteric bacteria in day care centers. *Am. J. Epidemiol.* 118(4): 562-572.

Elsner, P. and H. I. Maibach. 1990. Microbiology of specialized skin: the vulva. *Seminars in Dermatol.* 9(4): 300-304.

Emmerson, A. M. 1989. The role of the skin in nosocomial infections: A review. *J. Chemotherapy* 1(1S): 12-18. **(Reference not available. Will be provided at a later date.)**

Emori, T. G. and R. P. Gaynes. 1993. An overview of nosocomial infections, including the role of the microbiology laboratory. *Clinical Microbiology Reviews* 6(4): 428-442.

Fahey, T. 1994. Good Manufacturing Practices (GMP) Are Critical for Non-production Employees Too! *Dairy, Food and Environmental Sanitation* 14(1): 8-10.

FCN. 1995. ERS Cites High Cost of Illness Due to Pathogens. Food and Chemical News. CRC Press, Inc., May 8, 1995. 37(11): 48-50.

FDA Public Health Service. 1993. The Food Code 1993.

Federal Register. 1994. Vol 59, No. 149. August 4, 1994. pp. 39888 - 39896.

Federal Register. 1995. Vol. 60, No. 23. February 3, 1995. pp. 6780 - 6783.

Feigen, R. D., P. G. Shackelford, J. Campbell, T. O. Lyles, M. Schechter and R. D. Lins. 1973. Assessment of the Role of Staphylococcus epidermidis as a Cause of Otitis Media. *Pediatrics* 52: 569-576.

Feingold, D. S., J. V. Hirschmann and J. J. Leyden. 1989. Bacterial Infections of the Skin. *J Amer. Acad. Dermatol.* 20: 469-475.

Fekety, R., K. H. Kim, D. Brown, D. H. Batts, M. Cudmore, and J. Silva. 1981. Epidemiology of antibiotic-associated colitis. Isolation of Clostridium difficile from the hospital environment. *Am. J. Med.* 70(4): 906-908.

Ferrieri, P., A. S. Jajani, L. W. Wannamaker, and S. S. Chapman. 1972. Natural history of impetigo. 1. Site sequence of acquisition and familial patterns of spread of cutaneous streptococci. *J. Clin. Invest.* 51: 2851-2862.

Finch, J. E., J. Prince, and M. Hawksworth. 1978. A Bacteriological Survey of the Domestic Environment. *J. Appl. Bacteriol.* 45: 357-364.

Finkey, M. B., N. C. Corbin, L. B. Aust, R. Aly, and H. I. Maibach. 1984. *In vivo* effect of antimicrobial soap bars containing 1.5% and 0.8% trichlorocarbanilide against two strains of pathogenic bacteria. *J. Soc. Cosmet. Chem.* 35: 351 - 355.

Food and Drug Administration (FDA). 1974. OTC Topical Antimicrobial Products and Drug and Cosmetic Products Proposed Rules. 39 *Federal Register* 33102 - 33141. September 6, 1974.

Food and Drug Administration (FDA). 1978. Topical Antimicrobial Products Tentative Final Monograph. 43 *Federal Register* 1210 - 1249. January 6, 1978.

Food and Drug Administration (FDA). 1991. Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for First Aid Antiseptic Drug Products. 56 *Federal Register* 33644 - 33680. July 22, 1991.

Food and Drug Administration (FDA). 1994. Tentative Final Monograph for Health-Care Antiseptic Drug Products; Proposed Rule. 59 *Federal Register* 31402 - 31451. June 17,1994.

Fornasini, M., R. R. Reves, B. E. Murray and L. K. Pickering. 1992. Trimethoprim-resistant Escherichia coli in households of children attending day care centers. *J. Infect. Dis.* 166(2): 326-330.

Foulke, J. 1994. How to outsmart dangerous E. coli strain. *FDA Consumer* Jan/Feb. 1994: 7-11.

Frosch, P. J. 1982. Irritancy of Soaps and Detergent Bars. In Frost, P. and S. N. Horowitz (Eds.) Principles of Cosmetics for the Dermatologist. C. V. Mosby & Co., 5-12.

Frosch, P. J. and A. M. Kligman. 1979. The Soap Chamber Test. *J. Amer. Acad. Dermatol.* 1: 35-41.

Galle, P. C., H. D. Homesley, and A. L. Rhyne. 1978. Reassessment of the Surgical Scrub. *Surgery, Gynecology & Obstetrics* 147: 215-218.

Garibaldi, R. A. 1988. Prevention of Intraoperative Wound Contamination with Chlorhexidine Shower and Scrub. *J. Hosp. Infect.* 11(B): 5-9.

Garner, F. S. and M. S. Favero. 1985. CDC guideline for handwashing and hospital environmental control, 1985. *Infect. Control* 7: 1-20.

Gerba, C., C. Wallis, and J. Melnick. 1975. Microbiological Hazards of Household Toilets: Droplet Production and the Fate of Residual Organism. *Appl. Microbiol.* 30(2): 229-237.

Givens, C. D. and R. P. Wenzel. 1980. Catheter-associated urinary tract infections in surgical patients: a controlled study on the excess morbidity and costs. *J Urol.* 124: 646-648.

Goodman, R. A., M. T. Osterholm, D. M. Granoff, and L. K. Pickering. 1984. Infectious Diseases and Child Care. *Pediatrics* 74:134-139.

Goodman, R. A. and S. L. Solomon. 1991. Transmission of Infectious Diseases in Outpatient Health Care Settings. *J. Am. Med. Assoc.* 265(18): 2377-2381.

Haley, R. W. 1987. Incidence and Nature of Endemic and Epidemic Nosocomial Infections. In Bennett, J. V. and P. S. Brachman (Eds.) Hospital Infections. Second Edition. Little, Brown and Company, Boston. pp. 359-374.

Haley, R. W., D. H. Culver, J. W. White, W. M. Morgan, and T. G. Emori. 1985. The nationwide nosocomial infection rate. *Am. J. Epidemiol.* 121(2): 159-167.

Haley, R. W., D. R. Schaberg, K. B. Crossley, S. D. von Allmen, J. E. McGowan, Jr. 1981. Extra charges and prolongation of stay attributable to nosocomial infections: A prospective interhospital comparison. *Am. J. Med.* 70: 51-58.

Haley, R. W., D. R. Schaberg, S. D. von Allmen, and J. E. McGowen, Jr. 1980. Estimating the extra charges and prolongation of hospitalization due to nosocomial infections: A comparison of methods. *J. Infect. Dis.* 141: 248-257.

Harris, C. 1989. MIC tests are not suitable for assessing antiseptic handwashes. *J. Hosp. Infect.* 13: 95.

Harris, J. R., J. Mariano, J. G. Wells, B. J. Payne, H. D. Donnell, and M. L. Cohen. 1985. Person-to-person Transmission in an Outbreak of Enteroinvasive Escherichia coli. *Am. J. Epidemiol.* 122(2): 245-252.

Hay, R. J. 1993. Skin Disease. British Medical Bulletin 49(2): 440-453.

Hlady, W. G., J. V. Bennett, A. Samadi, J. Begum, A. Hafez, A. I. Tarafdar, and, J. R. Boring. 1992. Neonatal Tetanus in Rural Bangladesh: Risk Factors and Toxoid Efficacy. *Am. J. Public Health* 82(10): 1365-1369.

Holaday, B., R. Pantell, C. Lewis, and C. L. Gillis. 1990. Patterns of Fecal Coliform Contamination in Day-Care Centers, *Public Health Nursing* 7(4): 224-228.

Holloway, P. M., J. H. Platt, G. Reybrouck, H. A. Lilly, S. Mehtar, and Y. Drabu. 1990. A Multi-centre Evaluation of Two Chlorhexidine-Containing Formulations for Surgical Hand Disinfection. *J. Hosp. Infect.* 16: 151-159.

Horan, T., D. Culver, W. Jarvis, G. Emori, S. Banerjee, W. Martone, and C. Thornsberry. 1988. Pathogens causing Nosocomial Infections. Preliminary data from the national Nosocomial Infections Surveillance System. *The Antimicrobic Newsletter* 5(9): 65-67. **(Reference not available. Will be provided at a later date.)**

Isenberg, H. D. and R. R. D'Amato. 1994. Indigenous and Pathogenic Microorganisms of Humans, Chapter 2. In Balows, A. (Ed.) Manual of Clinical Microbiology. Fifth Edition. American Society for Microbiology, Washington, D. C. pp. 2-14.

Jarvis, W. R. 1991. Nosocomial outbreaks: The Centers for Disease Control's Hospital Infections Program experience, 1980-1990. *Am. J. Med.* 91(suppl. 3B): 101-106.

Jones, H. E., J. K. Aston, C. W. Lewis, G. W. Sorensen, and, W. A. Akers. 1976. Environmental Factors and Skin Diseases. *Military Medicine* 237-243.

Kadar, V. and R. A. Osbourn. 1974. The Mildness of Soaps in the Care of Infants' Skin: A Comparative Study. *Current Therapeutic Research* 16(5): 452-456.

Kahn, M. U. 1982. Interruption of Shigellosis by Handwashing. *Trans. Royal Soc. Trop. Med. Hyg.* 76 (2): 164-168.

Kaltenhalter, E., R. Waterman, and P. Cross. 1991. Faecal Indicator Bacteria on the Hands and the Effectiveness of Handwashing in Zimbabwe. *J. Trop. Med. and Hyg.* 94: 358-363.

Kay, C. R. 1962. Sepsis in the Home. *Brit. Med. J.* April 14, 1048-1052.

Keeler, E. B., K. L. Kahn, D. Draper, J. M. Sherwood, L. V. Rubenstein, E. J. Reinish, J. Kosecoff, and R. H. Brook. 1990. Changes in sickness at admission following the introduction of the prospective payment system. *J. Am. Med. Assoc.* 264(15): 1962-1968.

Kretzner, E. and E. Larson. 1995. Do Antiseptic Agents Reduce Surgical Wound Infections. Preoperative Bathing, Operative Site Preparation, Surgical Hand Scrubs. In Rutala W. A., (Ed.) Chemical Germicides in Healthcare International Symposium, 1994. Assoc. For Professionals in Infection Control and Epidemiology. Wash., D. C., Polyscience Publishers, Morin Heights, PQ, Canada. pp. 149-161.

Laborde, D. J., K. A. Weigle, D. J. Weber and J. B. Kotch. 1993. Effect of fecal contamination on diarrheal illness rates in day-care centers. *Am. J. Epidemiol.* 138(4): 243-255.

Lacour, M. and C. Hauser. 1993. The role of microorganisms in atopic dermatitis. *Clin. Rev. in Allergy* 11: 491-522.

Larson, E. 1988. A Causal Link Between Handwashing and Risk of Infection? Examination of the Evidence. *Infect. Control Hosp. Epidemiol.* 9(1): 28-36.

Larson, E. L. 1994. Draft APIC guideline for Hand Washing and Hand Antisepsis in Health Care Settings. *Am. J. Infect. Control* 22(5): 25A-47A.

Larson, E. L., J. J. Leyden, K. J. McGinley, G. L. Grove, and G. H. Talbot. 1986. Physiologic and microbiologic changes in skin related to frequent hand washing. *Infect. Control* 7(2): 59-63.

Larson, E. and M. L. Rotter. 1990. Handwashing: Are Experimental Models a Substitute for Clinical Trials? Two Viewpoints. *Infect. Control Hosp. Epidemiol.* 11(2): 63-66.

Laufman, H. 1989. Current Use of Skin and Wound Cleansers and Antiseptics. *Am. J. Surgery* 157: 359-365.

Lee, L. A., S. M. Ostroff, H. B. McGee, D. R. Johnson, F. P. Downes, D. N. Cameron, N. H. Bean, and P. M. Griffin. 1991. An Outbreak of Shigellosis at an Outdoor Music Festival. *Am. J. Epidemiol. 133* (6): 608-615.

Leroy, O. and M. Garenne. 1991. Risk Factors of Neonatal Tetanus in Senegal. *Int. J. Epidemiol.* 20(2): 521-526.

Leyden, J. J., R. Stewart, and A. M. Kligman. 1979. Updated in-vivo Methods for Evaluating Topical Antimicrobial Agents on Human Skin. *J. Invest. Dermatol.* 72(4): 165-170.

Leyden, J. J., K. J. McGinley, E. Holzle, J. N. Labows, and A. M. Kligman. 1981. The microbiology of the human axilla and its relationship to axillary odor. *J. Invest. Dermatol.* 77: 413-416.

Lilly, H. A. and E. J. Lowbury. 1974. Disinfection of the Skin with Detergent Preparations of Irgasan DP 300 and Other Antiseptics. *Brit. Med. J.* 4: 372-374.

Lilly, H. A., E. J. L. Lowbury, and M. D. Wilkins. 1979. Limits to Progressive Reduction of Resident Skin Bacteria by Disinfection. *J. Clin. Pathol.* 32: 382-385.

Lockhart, J. D. 1973. Hexachlorophene and the Food and Drug Administration. *J. Clin. Pharmacol.* 13: 445-60.

Lopes, J. A. 1991. Food- and Water-Infective Microorganisms. In Block, S. S. (Ed.) Disinfection, Sterilization, and Preservation. Fourth Edition. Lea & Febiger, Philadelphia. pp. 773-787.

Lowbury, E. J. L., H. A. Lilly, and J. B. Bull. 1964. Disinfection of Hands: Removal of Transient Organisms. *Brit. Med. J.* 2: 230-233.

Lowbury, E. L. 1965. Removal of Bacteria from the Operation Site. In Skin Bacteria and Their Role in Infections, McGraw-Hill. pp. 263-275.

Lowbury, E. L. 1981. Topical Antimicrobials: Perspectives and Issues. In Maibach, H. and R. Aly (Eds.) Skin Microbiology: Relevance to Clinical Infection. Springer-Verlag, New York. pp. 158-168.

Lukacovic, M. F., F. E. Dunlap, S. E. Michaels, M. O. Visscher, and D. D. Watson. 1988. Forearm Wash Test to Evaluate the Clinical Mildness of Cleansing Products. *J. Soc. Cosmet. Chem.* 39: 355-366.

Maki, D. G. 1978. Control of Colonization and Transmission of Pathogenic Bacteria in Hospital. *Ann. Intern. Med.* 89(2): 777-780.

Maki, D. G. 1989. The Use of Antiseptics for Hand Washing by Medical Personnel. *J. Chemotherapy* Vol. 1, Supplement 1: 3-11.

Maki, D. G., M. Ringer, and C. J. Alvarado. 1991. Prospective Randomized Trial of Povidone-Iodine, Alcohol, and Chlorhexidine for Prevention of Infection Associated with Central Venous and Arterial Catheters. *Lancet* 338: 339-343.

Marples, M. 1965. The Ecology of Human Skin. Charles Thomas, Springfield, IL. pp. 93 - 98; 169 - 177.

Marples, R. R. and A. G. Towers. 1979. A Laboratory Model for the Investigation of Contact Transfer of Microorganisms. *J. Hyg. (Camb.)* 82: 237-248.

Marzulli, F. N. and M. Bruch. 1981. Antibacterial Soaps: Benefits Versus Risks. In Maibach, H. I. and R. Aly (Eds.) Skin Microbiology: Relevance to Clinical Infection. Springer-Verlag, New York. pp. 125-134.

Mayo Clinic Health Letter. 1993. Handwashing. June 1993: 4.

McGinley, K. J., E. L. Larson, and J. J. Leyden. 1988. Composition and Density of Microflora in the Subungual Space of the Hand. *J. Clin. Microbiol.* 26(5): 950-953.

Meers, P. D. and G. A. Yeo. 1978. Shedding of Bacteria and Skin Squames after Hand Washing. *J. Hyg. (Camb.)* 81: 99-105.

Mendes, M. F. and D. J. Lynch. 1976. A Bacteriological Survey of Washrooms and Toilets. *J. Hyg. (Camb.)* 76: 183-190.

Miller, M. L., L. A. James-Davis, and L. E. Milanesi. 1994. A Field Study Evaluating the Effectiveness of Different Hand Soaps and Sanitizers. *Dairy, Food and Environmental Sanitation* 14(3): 155-160.

Miller, P.J. 1982. Semmelweis. *Infect. Control* 3(5): 405-409.

Mintz, E. D., F. M. Reiff, R. V. Tauxe. 1995. Safe Water Treatment and Storage in the Home. *J. Am. Med. Assoc.* 273: 948-953.

Mizuba, S. and W. Sheikh. 1986. Microbiological Evaluation of a New Aqueous 2% Chlorhexidine Gluconate Patient Skin Preparation on the Axilla and Abdomen. Abstracts of the Annual Meeting-1986.

Morrison, Jr., B. M. and M. Paye. 1994. A Comparison of Three *In vitro* Screening Tests with an *In vivo* Clinical Test to Evaluate the Irritation Potential of Antimicrobial Liquid Soaps. Preprints of the 18th IFSCC Congress, Venice, Italy, October 3-6, 1994, 611-622.

Morrow, A. L., I. T. Townsend, and L. K. Pickering, 1991. Risk of enteric infection associated with child day care. *Pediatr. Ann.* 20(8): 427-433.

Mulberry, G. 1994. Personal communication. Hill Top Biolabs, Inc., June 10, 1994.

Nahata, M. C. 1985. Handwashing Prevents Infection. *Drug Intelligence and Clinical Pharmacy* 19: 738.

Nielsen, M. L., D. Raahave, J. G. Stage, and T. Justesen. 1975. Anaerobic and Aerobic Skin Bacteria Before and After Skin-Disinfection with Chlorhexidine: An Experimental Study in Volunteers. *J. Clin. Pathol.* 28: 793-797.

Noble, W. C. 1983. Microbial Skin Disease. Chapters 1 - 4. Edward Arnold, London. pp. 1- 100.

Noble, W. C. (Ed.) 1993. The Skin Microflora and Microbial Skin Disease. Cambridge Univ. Press. Great Britain. pp. 73-101, 135-172.

Nokes, K. M. 1983. Prevention of Nosocomial Infections through Handwashing. *Med. Ultrasound* 7(3): 113-115.

Oblinger, J. L. (Ed.) 1988. Bacteria Associated with Foodborne Diseases. *Food Technology* April 1988, 181-200.

Ojajarvi, J. 1980. Effectiveness of Handwashing and Disinfection Methods in Removing Transient Bacteria after Patient Nursing. *J. Hyg. (Camb.)* 85: 193-203.

Osterholm, M. T., R. R. Reves, J. R. Murph, and L. K. Pickering. 1992. Infectious Diseases and Child Day Care. *Pediatr. Inf. Dis. J.* 11(8): S31-S41.

Paulson, D. S. 1993. Evaluation of Three Microorganism Recovery Procedures Used to Determine Handwash Efficacy. *Dairy, Food and Environmental Sanitation* 13(9): 520-523.

Paulson, D. S. 1994. A Comparative Evaluation of Different Hand Cleansers. *Dairy, Food and Environmental Sanitation* 14(9): 524-528.

Peters, F. and D. Flick-Filles. 1991. Hand Disinfection to Prevent Puerperal Mastitis (letter). *Lancet* 338: Sept. 28. p. 831.

Peterson, A. F. 1985. Microbiology of the Hands: Factors Affecting the Population. In Developments in Industrial Microbiology. Vol. 26, Proceedings of the 41st General Meeting of Society for Industrial Microbiology, Society for Industrial Microbiology, Washington, D. C., pp. 503-507.

Pether, J. V. and R. J. Gilbert. 1971. The Survival of Salmonella on Finger-tips and Transfer of the Organisms to Foods. *J. Hyg. (Camb.)* 69: 673-681.

Pickering, L. K., A. V. Bartlett, and W. E. Woodward. 1986. Acute infectious diarrhea among children in day care: Epidemiology and Control. *Rev. Inf. Dis.* 8(4): 539-547.

Platt, J. H. and R. A. Bucknall. 1988. MIC Tests are not Suitable for Assessing Antiseptic Handwashes. *J. Hosp. Infect.* 11: 396-397.

Price, P. B. 1938. The Bacteriology of Normal Skin: a New Quantitative Test Applied to a Study of the Bacterial Flora and the Disinfection Action of Mechanical Cleansing. *J. Infect. Dis.* 63: 301-318.

Quinn, B., R. Baker, and J. Pratt. 1994. Hurricane Andrew and a pediatric emergency department. *Annals of Emergency Medicine* 23(4): 737-741.

Rayan, G. M. and D. J. Flournoy. 1987. Microbiologic Flora of Human Fingernails. *J. Hand Surgery* 12A(4): 605-607.

Reiss-Levy, E., E. McAlister, and M. Richards. 1984. Handwashing and Antiseptics (letter). *Med. J. Aust.* 140(4): 245.

Restaino, L. and C. E. Wind. 1990. Antimicrobial Effectiveness of Hand Washing for Food Establishments. *Dairy, Food and Environmental Sanitation* 10(3): 136-141.

Reybrouck, G. 1986. Handwashing and Hand Disinfection. *J. Hosp. Infect.* 8: 5-23.

Roach, M. 1994. How to Win at GERM Warfare. *Health* July/Aug. pp. 77-80.

Roth, M. K. and G. K. Land. 1987. How to prevent infection in a home care patient. *RN* Nov. 1987: 61-70.

Roth, R. R. and W. D. James. 1989. Microbiology of the Skin: Resident Flora, Ecology, Infection. *J. Amer. Acad. Dermatol.* 20(3): 367-390.

Rotter, M. 1990. Surgical Hand Disinfection: Effect of Sequential Use of Two Chlorhexidine Preparations. *J. Hosp. Infect.* 16: 161-166.

Rotter, M., W. Koller, and G. Wewalka. 1980. Povidone-Iodine and Chlorhexidine Gluconate-containing Detergents for Disinfection of Hands. *J. Hosp. Infect.* 1: 149 - 158.

Sampson, H. A. 1992. Atopic dermatitis. *Annals of Allergy* 69: 469 - 479.

Sanderson, P. J. and P. Rawal. 1987. Contamination of the Environment of Spinal Cord Injured Patients of Organisms Causing Urinary-Tract Infection. *J. Hosp. Infect.* 10: 173-178.

Scala, D. D., G. E. Fischler, B. M. Morrison, Jr., R. Aly, and H. I. Maibach. 1994. Evaluation of antimicrobial bar soaps containing triclocarban. Abst. Ann. Mtg. Am. Academy of Dermatology.

Schachner, L., N. Simons Ling, and S. Press. 1983. A Statistical Analysis of a Pediatric Dermatology Clinic. *Pediatric Dermatol.* 1(2): 157-164.

Schoenknecht, F. D., L. D. Sabath, and C. Thornsberry. 1991. Susceptibility Tests: Special Tests. In Lennette, E. H., et al. (Eds.) Manual of Clinical Microbiology, Fourth Edition, American Society for Microbiology, Washington, D. C. pp. 1000-1008.

Scott, E., S. F. Bloomfield, and C. G. Barlow. 1982. An Investigation of Microbial Contamination in the Home. *J. Hyg. (Camb.)* 89: 279-293.

Selwyn, S. 1981. Microbial Interactions and Antibiosis. In Maibach, H. I. and R. Aly (Eds.) Skin Microbiology, Springer-Verlag, New York. pp. 63-74.

Selwyn, S. and H. Ellis. 1972. Skin Bacteria and Skin Disinfection Reconsidered. *Brit. Med. J.* 1: 136-140.

Sharko, P. T., R. I. Murahata, J. J. Leyden, and G. L. Grove. 1991. Arm Wash with Instrumental Evaluation — A Sensitive Technique for Differentiating the Irritation Potential of Personal Washing Products. *Journal of the Dermal Clinical Evaluation Society* 2: 19-27.

Sheena, A. Z. and B. E. Stiles. 1983. Efficacy of Germicidal Hand Wash Agents Against Transient Bacteria Inoculated onto Hands. *J. Food Protection* 46(8): 722-727.

Shooter, R.A. et al. 1971. Isolation of Escherichia coli, Pseudomonas aeruginosa, and Klebsiella from Food in Hospitals, Canteens, and Schools. *Lancet* August 21, p. 390 - 392.

Simion, F. A., L. D. Rhein, G. L. Grove, J. M. Wojtkowski, R. H. Cagan, and D. D. Scala. 1991. Sequential Order of Skin Responses to Surfactants During a Soap Chamber Test. *Contact Dermatitis* 25: 242-249.

Smith, P. W. 1984. Infection Control Measures: The Environmental Reservoir. In Smith, P. W. (Ed.) Infection Control in Long Term Care Facilities. John Wiley & Sons, New York. pp. 269-334.

Stanton, B. F. and J. D. Clemens. 1987. An Educational Intervention for Altering Water-Sanitation Behaviors to Reduce Childhood Diarrhea in Urban Bangledesh II. A Randomized Trial to Assess the Impact of Intervention on Hygienic Behaviors and Rates of Diarrhea. *Am. J. Epidemiol.* 125(2): 292-301.

Stern, R. S. and Nelson, C. 1993. The Diminishing Role of the Dermatologist in the Office-Based Care of Cutaneous Diseases. *J. Amer. Acad. Dermatol.* 29(5): 773 - 777.

Stiles, M. E. and A. Z. Sheena. 1987. Efficacy of Germicidal Hand Wash Agents in Use in a Meat Processing Plant. *J. Food Protection* 50(4): 289-295.

Story, P. 1952. Testing of Skin Disinfectants. *Brit. Med. J.* Nov. 22, 1952. pp. 1128-1130.

Strube, D. D., S. W. Koontz, R. I. Murahata, and R. I. Theiler. 1989. The Flex Wash Test: A Method for Evaluating the Mildness of Personal Washing Products. *J. Soc. Cosmet. Chem.* 40: 297-306.

Taber, D., A. B. Ward, and F. Yackovich. 1969. Use of An Antimicrobial Soap in the Treatment of Erythrasma of the Toe Webs. *Cutis* 5(8): 991-993.

Taplin, D. 1981. Chapter 15. Chlorhexidene and Clinical Infections. In Maibach, H. and R. Aly (Eds.) Skin Microbiology: Relevance to Clinical Infection. Springer-Verlag, New York. pp. 113-124.

Taplin, D., L. Lansdell, A. M. Allen, R. Rodriguez, and A. Cortes. 1973. Prevalence of Streptococcal Pyoderma in Relation to Climate and Hygiene. *Lancet* 1:501-503.

Theiler, R. F., C. L. Schmit, and J. R. Rogeim. 1983. Application of a New Microbiological Technique to the Study of Antiperspirant and Deodorant Soap Efficacy. *J. Soc. Cosmet. Chem.* 34: 351 - 359.

Thompson, S. C., 1994. Infectious Diarrhea in Children: Controlling Transmission in the Child Care Setting. *J. Paediatr. Child Health* 30: 210-219.

Todd, E. C. 1983. Factors that Contributed to Foodborne Disease in Canada, 1973-1977. *J. Food Protection* 46(8): 737-747.

Todd, E. C. 1985a. Economic Loss from Foodborne Disease Outbreaks Associated with Foodservice Establishments. *J. Food Protection* 48(2): 169-180.

Todd, E. C. 1985b. Economic Loss from Foodborne Disease and Non-illness Related Recalls Because of Mishandling by Food Processors. *J. Food Protection* 48(7): 621-633.

Trepeta, R. W. and S. C. Edburg. 1984. Methyl Umbelliferyl-beta-D-Glucuronide-Based Medium for Rapid Isolation and Identification of Escherichia coli. *J. Clin. Microbiol.* 19(2): 172-174.

US Department of Agriculture. 1974. Guidelines for Obtaining Authorization of Compounds to Be Used in Meat and Poultry Plants. In USDA Food Safety and Inspection Service Agriculture Handbook No. 562. Oct. 1974.

USDA Food Safety and Inspection Service. 1993. List of Proprietary Substances. Publication No. 1419. January 1993.

USDA. 1994. Personal Communication to J. R. Keenan, December 9, 1994.

Van, R., A. L. Morrow, R. R. Reves and L. K. Pickering. 1991. Environmental Contamination in Child Day-Care Centers. *Am. J. Epidemiol.* 133(5): 460-470.

Verweij, P. E., M. van Egmond, D. J. Bac, J. G. van der Schroeff and R. P. Monton. 1991. Hygiene, Skin Infections and Types of Water Supply in Venda, South Africa. *Trans. Royal Soc. Trop. Med. Hyg.* 85: 681-684.

Weingold, S. E., J. J. Guzewich, and J. K. Fudala. 1994. Use of Foodborne Disease Data for HACCP Risk Assessment. *J. Food Protection* 57(9): 820-830.

Wenzel, R. P. 1989. Epidemiology of Hospital-Acquired Infections. In Balows, A. (Ed.) Manual of Clinical Microbiology, Fifth Edition. American Society for Microbiology, Washington, D. C. pp. 147-150.

Wey, S. B., M. Mori, M. A. Pfaller, R. F. Woolson, and R. P. Wenzel. 1988. Hospital-Acquired Candidemia: The Attributable Mortality and Excess Length of Stay. *Arch. Inter. Med.* 148: 2642-2645.

Williams, R. E. A. and R. M. Mackie. 1993. The staphylocci: Importance of their Control in the Management of Skin Disease. *Dermatologic Therapy* 11(1): 201-206.

Williamson, P. and A. M. Kligman. 1965. A New Method for the Quantitative Investigation of Cutaneous Bacteria. *J. Invest. Dermatol.* 45(6): 498-503.

Wilson, A. P., R. N. Gruneberg, T. Treasure, and M. F. Sturridge. 1987. The Effect of Antibiotic Prophylaxis and Topical Antiseptics on the Bacterial Flora of the Skin after Cardiac Surgery. *J. Hosp. Infect.* 10: 58-66.

Wilson, J. M., G. N. Chandler, Muslihatun, and Samiluddin. 1991. Handwashing Reduces Diarrhea Episodes Study in Lombok, Indonesia. *Trans. Royal Soc. Trop. Med. Hyg.* 85: 819-812.

Wilson, J. M. and G. N. Chandler. 1993. Sustained Improvements in Hygiene Behavior Amongst Village Women in Lombok, Indonesia. *Trans. Royal Soc. Trop. Med. Hyg.* 87: 615-616.

Wilson, P. E. 1970. A Comparison of Methods for Assessing the Value of Antimicrobial Soaps. *J. Appl. Bact.* 33: 574-581.

Yackovich, F. and J. E. Heinze. 1985. Evaluation of Substantivity and Antimicrobial Activity of Soap Bars on Human Skin by an In-Vivo Agar Patch Method. *J. Soc. Cosmet. Chem.* 36: 231-236.

Yackovich, F., N. K. Poulsen, and J. E. Heinze. 1986. Validation of the Agar Patch Test Using Soap Bars which Deposit Different Amounts of Triclocarban, *J. Soc. Cosmet. Chem.* 37: 99-104.

Yackovich, F., C. A. Wagner, and J. E. Heinze. 1989. Validation of the Agar Patch Test with an Antimicrobial Liquid Soap and Comparison with the Finger Imprint Method, *J. Soc. Cosmet. Chem.* 40: 265-271.

Zimakoff, J., V. Thamdrup, W. Petersen, and J. Scheibel. 1988. Recurrent Staphylococcal Furunculosis in Families. *Scand. J. Infect. Dis.* 20: 403-405.